IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KATHERINE CROCKETT, **Plaintiff,** **v.** **LUITPOLD PHARMACEUTICALS, INC.; AMERICAN REGENT, INC.; DAIICHI SANKYO, INC.; DAIICHI SANKYO US HOLDINGS, INC.; and VIFOR (INTERNATIONAL) AG,** **Defendant.**	**CIVIL ACTION** **NO. 19-276**

MEMORANDUM OPINION

This drug product liability case arises out of the alleged injuries Plaintiff Katherine Crockett sustained after being administered Injectafer, an iron-replacement medication used to treat iron deficiency anemia. Plaintiff attributes her injuries to hypophosphatemia ("HPP"), a condition marked by low blood phosphorus levels. In light of the parties' familiarity with the case, further factual background is omitted here. Pursuant to *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), Defendants seek to exclude opinions by Dr. Maureen Achebe on the topic of Injectafer's drug labeling, contending that Achebe cannot challenge the content of the Injectafer label and its warnings related to HPP on the basis she is not a regulatory expert and cannot opine "about how other physicians would interpret the language used in the Injectafer Prescribing Information" because she has "no expertise that would allow her to read the minds of prescribing physicians[.]" For the reasons below, Defendants' motion will be denied.

I. LEGAL STANDARDS

Daubert established a "gatekeeping role" for trial courts in admitting expert testimony. *Oddi v. Ford Motor Co.*, 234 F.3d 136, 144 (3d Cir. 2000) (quoting *Daubert*, 509 U.S. at 597).

The *Daubert* standard is codified in Federal Rule of Evidence 702, which provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702; *see Durando v. Trustees of Univ. of Pennsylvania*, 2022 WL 2467080, at *1 (E.D. Pa. July 6, 2022). The rule "embodies a trilogy of restrictions on expert testimony: qualification, reliability, and fit." *Durando*, 2022 WL 2467080, at *1 (quoting *Schneider ex rel. Est. of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003)). The proponent of expert testimony has the burden of establishing its admissibility by a preponderance of evidence. *Oddi*, 234 F.3d at 144 (citing *Daubert*, 509 U.S. at 593 n.10).

II. DISCUSSION

A. Scope of Achebe's Expert Testimony

As a preliminary matter, Defendants mischaracterize the scope of Achebe's proffered testimony. Achebe does not offer her opinions on the adequacy of the Injectafer label from a regulatory perspective: she offers them from the perspective of a physician with vast experience with iron deficiency conditions and related treatments. Specifically, she concludes that the "labeling for Injectafer" was "insufficient to warn of the true risks of . . . hypophosphatemia" in light of her "research in the field and review of pertinent literature." With this in mind, as set forth below, under the trilogy of factors Defendants' Motion shall be denied.

B. Qualifications

To satisfy *Daubert*'s qualification requirement, an expert must possess "specialized knowledge regarding the area of testimony." *Betterbox Comm'ns Ltd. v. BB Techs., Inc.*, 300

F.3d 325, 327 (3d Cir. 2002) (internal quotation omitted). "The basis of this specialized knowledge 'can be practical experience as well as academic training and credentials.'" *Waldorf v. Shuta*, 142 F.3d 601, 625 (3d Cir. 1998) (citing *American Tech. Resources v. United States*, 893 F.2d 651, 656 (3d Cir. 1990); and *Hammond v. International Harvester Co.*, 691 F.2d 646, 653 (3d Cir. 1982)). The qualification requirement is generally interpreted "liberally," *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008), and "a broad range of knowledge, skills, and training qualify an expert as such." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994) (citation omitted).

Achebe is an assistant professor of medicine at Harvard Medical School; the clinical director of the Division of Hematology at the Dana Farber Cancer Institute; and the medical director of the Ambulatory Infusion Center at Brigham and Women's Hospital. She oversees the infusion of thousands of patients annually including with treatments involving intravenous iron formulations. She consults with "providers who prescribe ferric carboxymaltose (FCM or Injectafer[])[.]" She also oversees "clinical management of patients with iron deficiency[.]" Moreover, she has conducted clinical research and authored articles "on the clinical use of various iron formulations, including ferric carboxymaltose" and "has conducted research and authored articles on the comparative risk of hypophosphatemia between certain iron IV formulations."

In light of her wealth of experience, Achebe is qualified to render opinions on whether warnings provided in the Injectafer labeling were adequate to inform prescribing physicians of the drug's risks as to HPP. *See, e.g.*, *Rowland v. Novartis Pharms. Corp.*, 9 F. Supp.3d 553, 569 (W.D. Pa. 2014) (concluding medical expert could testify as to adequacy of drug labeling and warnings from the perspective of a prescribing physician).

While Defendants respond that Achebe never *personally* prescribed Injectafer (which the cited portion of her testimony appears to support), they cite no authority supporting the proposition that she cannot testify as to the adequacy of warnings in Injectafer's labeling from the perspective of a reasonable physician in light of her broad and varied experience with iron deficiency drugs, including Injectafer. On the basis of her experience overseeing infusions of similar drugs, consultation with prescribers of Injectafer, and her research on such drugs and related conditions, she is qualified to opine on the adequacy of Injectafer's warnings in respect to HPP from a physician's perspective—regardless of whether she personally prescribed Injectafer.

Moreover, while doctors generally may not "opine as experts about what all doctors generally consider in making prescription decisions," they may nonetheless "opine on the medical facts and science regarding the risks and benefits of the [] drugs in question and to compare that knowledge with what was provided in the text of labeling and warnings on the [] drugs in question." *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig.*, 2000 WL 876900, at *11 (E.D. Pa. June 20, 2000). Achebe's proffered testimony is within this permissible scope.

C. Reliability

An expert's conclusions must "reliably flow from the facts known to the expert and the methodology used." *Oddi*, 234 F.3d at 146 (citation omitted). "To satisfy the reliability requirement, 'the expert must have good grounds for his or her belief,' not 'subjective belief or unsupported speculation.'" *T.N. Incorporation, Ltd. v. Fid. Nat'l Info. Servs., Inc.*, 2021 WL 5980048, at *2 (E.D. Pa. Dec. 17, 2021) (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 742). Beyond the traditional *Daubert* reliability factors, which focus on assessing scientific methods, *see In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 2020

WL 6887885, at *3 (E.D. Pa. Nov. 24, 2020), the reliability inquiry may also focus upon an expert's "personal knowledge or experience." *Id.* at *26 (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999)). "The reliability test is flexible and a district court enjoys 'broad latitude when it decides how to determine reliability.'" *Durando*, 2022 WL 2467080, at *2 (quoting *Kumho Tire*, 526 U.S. at 142). When reliability questions go to the weight of an expert's proposed testimony rather than its admissibility, they become an issue suitable for the jury. *See id.* at *4.

Doctors are able to rely on their experience to opine about what a reasonable doctor should know or how a reasonable doctor would interpret a drug warning. *See In re Suboxone*, 2020 WL 6887885, at *26 (listing cases). Moreover, medical experts can testify as to the adequacy of drug labeling and warnings based on their experience as physicians. *See, e.g.*, *Rowland*, 9 F. Supp.3d at 569. This is what Achebe does in her report.

While Defendants contest Achebe's methodology by pointing to a portion of her deposition testimony stating she did not recognize a specific table within the Injectafer labeling, that alone does not support, as Defendants maintain, that Achebe was sufficiently unfamiliar with the relevant details of the Injectafer label to render her related testimony inadmissible. Such argument is better suited for cross-examination. *See Durando*, 2022 WL 2467080, at *4 (stating that arguments about reliability that go to the weight of proposed testimony are generally a matter for the jury).

D. Fit

"In assessing whether an expert's proposed testimony fits, [the question is] whether the proffered testimony is sufficiently tied to the facts of the case such that it will aid the jury in resolving a factual dispute." *United States v. Schiff*, 602 F.3d 152, 173 (3d Cir. 2010) (internal

quotation, ellipses, and citation omitted). The fit of testimony goes "primarily to relevance." *Daubert*, 509 U.S. at 591. Relevancy presents a "relatively low obstacle to clear." *Hausknecht v. John Hancock Life Ins. Co. of New York*, 2022 WL 1664362, at *8 (E.D. Pa. May 25, 2022) (citing *United States v. Ford*, 481 F.3d 215, 219-20 (3d Cir. 2007)). "The Rules of Evidence embody a strong preference for admitting any evidence that may assist the trier of fact." *Pineda*, 520 F.3d at 243 (citation omitted).

Achebe's opinions on the adequacy of the warnings in Injectafer's labeling from a physician's perspective are relevant and have a connection with the "particular disputed factual issues in the case[]" (in that Plaintiff's claims are predicated on Defendants' purported failure to adequately warn of Injectafer's risks of HPP in the drug's labeling). *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 743 (quoting *United States v. Downing*, 753 F.2d 1224, 1237 (3d Cir. 1985)).

Defendants' concerns as to the fit of Achebe's testimony, based on the learned intermediary doctrine and Injectafer's regulatory approval, do not negate the relevance of Achebe's testimony; instead, they are better addressed in the adversarial process, at trial, during cross-examination. *See, e.g.*, *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 2015 WL 5783603, at *9 (E.D. Pa. Oct. 5, 2015) (concluding that certain challenges to the fit of expert opinions did not warrant exclusion and were "more appropriately addressed through cross-examination or competing expert testimony").

Accordingly, Defendants' motion to exclude Achebe's labeling opinions shall be denied. An appropriate order follows.

BY THE COURT:

/S/WENDY BEETLESTONE, J.

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